

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
US Department of Commerce  
United States Patent and Trademark  
Office, PCT  
2011 South Clark Place Room  
CP2/5C24  
Arlington, VA 22202  
ETATS-UNIS D'AMERIQUE  
in its capacity as elected Office

Date of mailing (day/month/year) 18 May 2001 (18.05.01)	
International application No. PCT/JP00/06100	Applicant's or agent's file reference 1230
International filing date (day/month/year) 07 September 2000 (07.09.00)	Priority date (day/month/year) 07 September 1999 (07.09.99)
Applicant KOHNO, Hiroaki et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
29 March 2001 (29.03.01)

☐ in a notice effecting later election filed with the International Bureau on:  
\_\_\_\_\_

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Kiwa Mpay Telephone No.: (41-22) 338.83.38
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# PCT

## REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference  
(if desired) (12 characters maximum)

1230

### Box No. I TITLE OF INVENTION

METHOD AND REAGENT FOR DETECTION OF TRICHOHECENE MYCOTOXINS

### Box No. II APPLICANT

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

KYOWA MEDEX CO., LTD.

1-1, Irifune 2-chome, Chuo-ku, Tokyo 104-0042  
Japan

☐ This person is also inventor.

Telephone No. 03-3282-0036

Facsimile No. 03-3282-1527

Teleprinter No.

State (that is, country) of nationality: JP

State (that is, country) of residence: JP

This person is applicant for the purposes of:

☐ all designated States

☒ all designated States except the United States of America

☐ the United States of America only

☐ the States indicated in the Supplemental Box

### Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

Hiroaki Kohno

c/o Kyowa Medex Research Laboratories  
KYOWA MEDEX CO., LTD.  
600-1, Aza-Kamiyamaji, Minamiishiki,  
Nagaizumi-cho, Sunto-gun, Shizuoka 411-0932 Japan

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality: JP

State (that is, country) of residence: JP

This person is applicant for the purposes of:

☐ all designated States

☐ all designated States except the United States of America

☒ the United States of America only

☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

### Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:

☒ agent

☐ common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

Kazuyuki Iwahashi

KYOWA HAKKO KOGYO CO., LTD.  
Intellectual Property Department  
6-1, Ohtemachi 1-chome, Chiyoda-ku, Tokyo  
100-8185 Japan

Telephone No. 03-3282-0036

Facsimile No. 03-3282-1527

Teleprinter No.

☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III <b>FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)</b>	
<i>If none of the following sub-boxes is used, this sheet should not be included in the request.</i>	
<p><b>Name and address:</b> <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</i></p> <p>Yuriko Hashimoto</p> <p>c/o Kyowa Medex Research Laboratories KYOWA MEDEX CO., LTD. 600-1, Aza-Kamiyamaji, Minamiishiki, Nagaizumi-cho, Sunto-gun, Shizuoka 411-0932 Japan</p>	<p><b>This person is:</b></p> <p><input type="checkbox"/> applicant only</p> <p><input checked="" type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only <i>(If this check-box is marked, do not fill in below.)</i></p>
State (that is, country) of nationality:    JP	State (that is, country) of residence:    JP
<p><b>This person is applicant for the purposes of:</b></p> <p><input type="checkbox"/> all designated States    <input type="checkbox"/> all designated States except the United States of America    <input checked="" type="checkbox"/> the United States of America only    <input type="checkbox"/> the States indicated in the Supplemental Box</p>	
<p><b>Name and address:</b> <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</i></p> <p>Takumi Yoshizawa</p> <p>1212-6, Hikami, Miki-cho, Kita-gun, Kagawa 761-0612 Japan</p>	<p><b>This person is:</b></p> <p><input type="checkbox"/> applicant only</p> <p><input checked="" type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only <i>(If this check-box is marked, do not fill in below.)</i></p>
State (that is, country) of nationality:    JP	State (that is, country) of residence:    JP
<p><b>This person is applicant for the purposes of:</b></p> <p><input type="checkbox"/> all designated States    <input type="checkbox"/> all designated States except the United States of America    <input checked="" type="checkbox"/> the United States of America only    <input type="checkbox"/> the States indicated in the Supplemental Box</p>	
<p><b>Name and address:</b> <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</i></p>	<p><b>This person is:</b></p> <p><input type="checkbox"/> applicant only</p> <p><input type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only <i>(If this check-box is marked, do not fill in below.)</i></p>
State (that is, country) of nationality:	State (that is, country) of residence:
<p><b>This person is applicant for the purposes of:</b></p> <p><input type="checkbox"/> all designated States    <input type="checkbox"/> all designated States except the United States of America    <input type="checkbox"/> the United States of America only    <input type="checkbox"/> the States indicated in the Supplemental Box</p>	
<p><b>Name and address:</b> <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</i></p>	<p><b>This person is:</b></p> <p><input type="checkbox"/> applicant only</p> <p><input type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only <i>(If this check-box is marked, do not fill in below.)</i></p>
State (that is, country) of nationality:	State (that is, country) of residence:
<p><b>This person is applicant for the purposes of:</b></p> <p><input type="checkbox"/> all designated States    <input type="checkbox"/> all designated States except the United States of America    <input type="checkbox"/> the United States of America only    <input type="checkbox"/> the States indicated in the Supplemental Box</p>	
<p><input type="checkbox"/> Further applicants and/or (further) inventors are indicated on another continuation sheet.</p>	

**Box No.V DESIGNATION OF STATES**

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be made):

**Regional Patent**

- ☒ **AP** ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, MZ Mozambique, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ **EA** Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ **EP** European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ **OA** OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côté d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other of protection or treatment desired, specify on dotted line)

**National Patent (if other kind of protection or treatment desired, specify on dotted line):**

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> <b>AE</b> United Arab Emirates                 | <input checked="" type="checkbox"/> <b>LC</b> Saint Lucia   |
| <input checked="" type="checkbox"/> <b>AG</b> Antigua and Barbuda                  | <input checked="" type="checkbox"/> <b>LK</b> Sri Lanka   |
| <input checked="" type="checkbox"/> <b>AL</b> Albania                              | <input checked="" type="checkbox"/> <b>LR</b> Liberia   |
| <input checked="" type="checkbox"/> <b>AM</b> Armenia                              | <input checked="" type="checkbox"/> <b>LS</b> Lesotho   |
| <input checked="" type="checkbox"/> <b>AT</b> Austria                              | <input checked="" type="checkbox"/> <b>LT</b> Lithuania   |
| <input checked="" type="checkbox"/> <b>AU</b> Australia                            | <input checked="" type="checkbox"/> <b>LU</b> Luxembourg  |
| <input checked="" type="checkbox"/> <b>AZ</b> Azerbaijan                           | <input checked="" type="checkbox"/> <b>LV</b> Latvia  |
| <input checked="" type="checkbox"/> <b>BA</b> Bosnia and Herzegovina               | <input checked="" type="checkbox"/> <b>MA</b> Morocco   |
| <input checked="" type="checkbox"/> <b>BB</b> Barbados                             | <input checked="" type="checkbox"/> <b>MD</b> Republic of Moldova   |
| <input checked="" type="checkbox"/> <b>BG</b> Bulgaria                             | <input checked="" type="checkbox"/> <b>MG</b> Madagascar  |
| <input checked="" type="checkbox"/> <b>BR</b> Brazil                               | <input checked="" type="checkbox"/> <b>MK</b> The former Yugoslav Republic of Macedonia   |
| <input checked="" type="checkbox"/> <b>BY</b> Belarus                              | <input checked="" type="checkbox"/> <b>MN</b> Mongolia  |
| <input checked="" type="checkbox"/> <b>BZ</b> Belize                               | <input checked="" type="checkbox"/> <b>MW</b> Malawi  |
| <input checked="" type="checkbox"/> <b>CA</b> Canada                               | <input checked="" type="checkbox"/> <b>MX</b> Mexico  |
| <input checked="" type="checkbox"/> <b>CH and LI</b> Switzerland and Liechtenstein | <input checked="" type="checkbox"/> <b>MZ</b> Mozambique  |
| <input checked="" type="checkbox"/> <b>CN</b> China                                | <input checked="" type="checkbox"/> <b>NO</b> Norway  |
| <input checked="" type="checkbox"/> <b>CR</b> Costa Rica                           | <input checked="" type="checkbox"/> <b>NZ</b> New Zealand   |
| <input checked="" type="checkbox"/> <b>CU</b> Cuba                                 | <input checked="" type="checkbox"/> <b>PL</b> Poland  |
| <input checked="" type="checkbox"/> <b>CZ</b> Czech Republic                       | <input checked="" type="checkbox"/> <b>PT</b> Portugal  |
| <input checked="" type="checkbox"/> <b>DE</b> Germany                              | <input checked="" type="checkbox"/> <b>RO</b> Romania   |
| <input checked="" type="checkbox"/> <b>DK</b> Denmark                              | <input checked="" type="checkbox"/> <b>RU</b> Russian Federation  |
| <input checked="" type="checkbox"/> <b>DM</b> Dominica                             | <input checked="" type="checkbox"/> <b>SD</b> Sudan   |
| <input checked="" type="checkbox"/> <b>DZ</b> Algeria                              | <input checked="" type="checkbox"/> <b>SE</b> Sweden  |
| <input checked="" type="checkbox"/> <b>EE</b> Estonia                              | <input checked="" type="checkbox"/> <b>SG</b> Singapore   |
| <input checked="" type="checkbox"/> <b>ES</b> Spain                                | <input checked="" type="checkbox"/> <b>SI</b> Slovenia  |
| <input checked="" type="checkbox"/> <b>FI</b> Finland                              | <input checked="" type="checkbox"/> <b>SK</b> Slovakia  |
| <input checked="" type="checkbox"/> <b>GB</b> United Kingdom                       | <input checked="" type="checkbox"/> <b>SL</b> Sierra Leone  |
| <input checked="" type="checkbox"/> <b>GD</b> Grenada                              | <input checked="" type="checkbox"/> <b>TJ</b> Tajikistan  |
| <input checked="" type="checkbox"/> <b>GE</b> Georgia                              | <input checked="" type="checkbox"/> <b>TM</b> Turkmenistan  |
| <input checked="" type="checkbox"/> <b>GH</b> Ghana                                | <input checked="" type="checkbox"/> <b>TR</b> Turkey  |
| <input checked="" type="checkbox"/> <b>GM</b> Gambia                               | <input checked="" type="checkbox"/> <b>TT</b> Trinidad and Tobago   |
| <input checked="" type="checkbox"/> <b>HR</b> Croatia                              | <input checked="" type="checkbox"/> <b>TZ</b> United Republic of Tanzania   |
| <input checked="" type="checkbox"/> <b>HU</b> Hungary                              | <input checked="" type="checkbox"/> <b>UA</b> Ukraine   |
| <input checked="" type="checkbox"/> <b>ID</b> Indonesia                            | <input checked="" type="checkbox"/> <b>UG</b> Uganda  |
| <input checked="" type="checkbox"/> <b>IL</b> Israel                               | <input checked="" type="checkbox"/> <b>US</b> United States of America  |
| <input checked="" type="checkbox"/> <b>IN</b> India                                | <input checked="" type="checkbox"/> <b>UZ</b> Uzbekistan  |
| <input checked="" type="checkbox"/> <b>IS</b> Iceland                              | <input checked="" type="checkbox"/> <b>VN</b> Viet Nam  |
| <input checked="" type="checkbox"/> <b>JP</b> Japan                                | <input checked="" type="checkbox"/> <b>YU</b> Yugoslavia  |
| <input checked="" type="checkbox"/> <b>KE</b> Kenya                                | <input checked="" type="checkbox"/> <b>ZA</b> South Africa  |
| <input checked="" type="checkbox"/> <b>KG</b> Kyrgyzstan                           | <input checked="" type="checkbox"/> <b>ZW</b> Zimbabwe  |
| <input type="checkbox"/> <b>KP</b> Democratic People's Republic of Korea           | <input type="checkbox"/> Check-box reserved for designating States which have become party to the PCT after issuance of this sheet: |
| <input checked="" type="checkbox"/> <b>KR</b> Republic of Korea                    |   |
| <input checked="" type="checkbox"/> <b>KZ</b> Kazakhstan                           |   |

**Precautionary Designation Statement:** In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)

<b>Box No. VI PRIORITY CLAIM</b>		<input type="checkbox"/> Further priority claims are indicated in the Supplemental Box.		
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country	regional application: regional Office	international application: receiving Office
item (1) 07.09.99	253443/99	JP		
item (2) 29.10.99	310185/99	JP		
item (3)				
<input checked="" type="checkbox"/> The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s): (1), (2)				
<i>* Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.</i>				
<b>Box No. VII INTERNATIONAL SEARCHING AUTHORITY</b>				
<b>Choice of International Searching Authority (ISA)</b> <i>(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):</i>		<b>Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority):</b> Date (day/month/year)      Number      Country (or regional Office)		
ISA / JP				
<b>Box No. VIII CHECK LIST; LANGUAGE OF FILING</b>				
This international application contains the following number of sheets: request : 4 description (excluding sequence listing part) : 38 claims : 8 abstract : 1 drawings : 5 sequence listing part of description : 0 <b>Total number of sheets : 56</b>		This international application is accompanied by the item(s) marked below: 1. <input checked="" type="checkbox"/> fee calculation sheet 2. <input type="checkbox"/> separate signed power of attorney 3. <input type="checkbox"/> copy of general power of attorney; reference number, if any: 4. <input type="checkbox"/> statement explaining lack of signature 5. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s): 6. <input type="checkbox"/> translation of international application into (language): 7. <input checked="" type="checkbox"/> separate indications concerning deposited microorganism or other biological material 8. <input type="checkbox"/> nucleotide and/or amino acid sequence listing in computer readable form 9. <input type="checkbox"/> other (specify):		
<b>Figure of the drawings which should accompany the abstract:</b>		<b>Language of filing of the international application:</b> JP		
<b>Box No. IX SIGNATURE OF APPLICANT OR AGENT</b>				
<i>Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).</i>				
Kazuyuki Iwahashi				

For receiving Office use only			
1. Date of actual receipt of the purported international application:  3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:  4. Date of timely receipt of the required corrections under PCT Article 11(2):  5. International Searching Authority (if two or more are competent): ISA / JP	2. Drawings:  <input type="checkbox"/> received:  <input type="checkbox"/> not received:  6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid.		

For International Bureau use only	
Date of receipt of the record copy by the International Bureau:	

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1230	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP00/06100	International filing date (day/month/year) 07 September 2000 (07.09.00)	Priority date (day/month/year) 07 September 1999 (07.09.99)
International Patent Classification (IPC) or national classification and IPC C12N 15/02, C12P 21/08, C12N 15/12, G01N 33/53, 33/577		
Applicant KYOWA MEDEX CO., LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 29 March 2001 (29.03.01)	Date of completion of this report 09 October 2001 (09.10.2001)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP00/06100

## I. Basis of the report

1. With regard to the **elements** of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP 00/06100

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-12, 14, 15, 18-40	YES
	Claims	13, 16, 17	NO
Inventive step (IS)	Claims	1-12, 18-40	YES
	Claims	13-17	NO
Industrial applicability (IA)	Claims	1-40	YES
	Claims		NO

**2. Citations and explanations**

Claims 13-17

Document 1: K. Ohtani et al., Toxicon (1988), Vol. 26, No. 11, pp. 1107-1111

Document 2: M. M. Abouzied et al., Applied and Environmental Microbiology (1993), Vol. 59, pp. 1264-1268

Document 3: W. L. Casale et al., Journal of Agricultural and Food Chemistry (1988), Vol. 36, No. 3, pp. 663-668

Document 4: M. J. Nicol et al., Food & Agricultural Immunology (1993), Vol. 5, no. 4, pp. 199-209

Document 1, Fig. 1., discloses a process for preparing a T-2 toxin complex with a protein, wherein the protein is bound to position 3 of a T-2 derivative having a 4-OAc and a 15-bound OAc, and the 3-hydroxyl group of T-2 is modified to acyloxy. Page 1109, line 28 to page 1110, line 1, and page 1110, lines 13-16, also disclose use of the hapten-protein complex to prepare a hapten-bound antibody, and for screening.

Document 2, Fig. 1, discloses a process for binding a protein to DNIV, wherein the protein is bound to a



modified DNIV having a 4-OAc, a 15-bound OAc and the 3-hydroxyl of DNIV is modified to acyloxy. The subsection "Immunization" of the section "Materials and methods" also discloses use of the DNIV-protein complex to prepare an antibody.

Document 3 discloses a process for preparing a monoclonal antibody against DON, wherein a DON-BSA complex is administered to mice in order to obtain a hybridoma; it also indicates that the complex of DON and carrier protein is prepared by binding to protein to 3-O-hemisuccinyl-DON (3-HS-DON).

Document 4 discloses binding a protein to 3-HG-DON to prepare a DON-protein complex. It also indicates that the resulting complex can be administered to mice to obtain a hybridoma in order to produce a monoclonal antibody.

Documents 3 and 4 disclose the use of a complex of DON 3-bound to a carrier protein for producing a monoclonal antibody; therefore the inventions set forth in Claims 13, 16 and 17 are not novel.

Documents 1 and 2 do not disclose production of a monoclonal-antibody-producing hybridoma using a complex prepared in Document 1 or 2; however, production of a monoclonal-antibody-producing hybridoma by applying a known technique for preparing an antibody is obvious to a person skilled in the art.

Claims 1-12 and 18-40

None of the documents cited in the international search report discloses or suggests a monoclonal antibody or antibody fragment therefrom described in Claim 1, 3 or

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

International application No.

PCT/JP 00/06100

5, or immunoassay using an aforementioned monoclonal antibody or antibody fragment therefrom.

PCT

国際予備審査報告

(法第12条、法施行規則第56条)  
[PCT36条及びPCT規則70]

REC'D 26 OCT 2001

WIPO

PCT

出願人又は代理人 の書類記号 1230	今後の手続きについては、国際予備審査報告の送付通知(様式PCT/ IPEA/416)を参照すること。	
国際出願番号 PCT/JP00/06100	国際出願日 (日.月.年) 07.09.00	優先日 (日.月.年) 07.09.99
国際特許分類(IPC) Int.Cl <sup>7</sup> C12N15/02, C12P21/08, C12N15/12, G01N33/53, G01N33/577		
出願人(氏名又は名称) 協和メデックス株式会社		

1. 国際予備審査機関が作成したこの国際予備審査報告を法施行規則第57条(PCT36条)の規定に従い送付する。
2. この国際予備審査報告は、この表紙を含めて全部で 4 ページからなる。
- ☐ この国際予備審査報告には、附属書類、つまり補正されて、この報告の基礎とされた及び/又はこの国際予備審査機関に対してした訂正を含む明細書、請求の範囲及び/又は図面も添付されている。  
(PCT規則70.16及びPCT実施細則第607号参照)  
この附属書類は、全部で ページである。

3. この国際予備審査報告は、次の内容を含む。
- I ☒ 国際予備審査報告の基礎
- II ☐ 優先権
- III ☐ 新規性、進歩性又は産業上の利用可能性についての国際予備審査報告の不作成
- IV ☐ 発明の単一性の欠如
- V ☒ PCT35条(2)に規定する新規性、進歩性又は産業上の利用可能性についての見解、それを裏付けるための文献及び説明
- VI ☐ ある種の引用文献
- VII ☐ 国際出願の不備
- VIII ☐ 国際出願に対する意見

国際予備審査の請求書を受理した日 29.03.01	国際予備審査報告を作成した日 09.10.01	
名称及びあて先 日本国特許庁(IPEA/JP) 郵便番号100-8915 東京都千代田区霞が関三丁目4番3号	特許庁審査官(権限のある職員) 新見 浩一 電話番号 03-3581-1101 内線 3448	4B 9162

## I. 国際予備審査報告の基礎

1. この国際予備審査報告は下記の出願書類に基づいて作成された。(法第6条(PCT14条)の規定に基づく命令に  
応答するために提出された差し替え用紙は、この報告書において「出願時」とし、本報告書には添付しない。  
PCT規則70.16, 70.17)

☒ 出願時の国際出願書類

- ☐ 明細書 第 \_\_\_\_\_ ページ、 出願時に提出されたもの  
明細書 第 \_\_\_\_\_ ページ、 国際予備審査の請求書と共に提出されたもの  
明細書 第 \_\_\_\_\_ ページ、 \_\_\_\_\_ 付の書簡と共に提出されたもの
- ☐ 請求の範囲 第 \_\_\_\_\_ 項、 出願時に提出されたもの  
請求の範囲 第 \_\_\_\_\_ 項、 PCT19条の規定に基づき補正されたもの  
請求の範囲 第 \_\_\_\_\_ 項、 国際予備審査の請求書と共に提出されたもの  
請求の範囲 第 \_\_\_\_\_ 項、 \_\_\_\_\_ 付の書簡と共に提出されたもの
- ☐ 図面 第 \_\_\_\_\_ ページ/図、 出願時に提出されたもの  
図面 第 \_\_\_\_\_ ページ/図、 国際予備審査の請求書と共に提出されたもの  
図面 第 \_\_\_\_\_ ページ/図、 \_\_\_\_\_ 付の書簡と共に提出されたもの
- ☐ 明細書の配列表の部分 第 \_\_\_\_\_ ページ、 出願時に提出されたもの  
明細書の配列表の部分 第 \_\_\_\_\_ ページ、 国際予備審査の請求書と共に提出されたもの  
明細書の配列表の部分 第 \_\_\_\_\_ ページ、 \_\_\_\_\_ 付の書簡と共に提出されたもの

2. 上記の出願書類の言語は、下記に示す場合を除くほか、この国際出願の言語である。

上記の書類は、下記の言語である \_\_\_\_\_ 語である。

- ☐ 国際調査のために提出されたPCT規則23.1(b)にいう翻訳文の言語  
☐ PCT規則48.3(b)にいう国際公開の言語  
☐ 国際予備審査のために提出されたPCT規則55.2または55.3にいう翻訳文の言語

3. この国際出願は、ヌクレオチド又はアミノ酸配列を含んでおり、次の配列表に基づき国際予備審査報告を行った。

- ☐ この国際出願に含まれる書面による配列表  
☐ この国際出願と共に提出されたフレキシブルディスクによる配列表  
☐ 出願後に、この国際予備審査(または調査)機関に提出された書面による配列表  
☐ 出願後に、この国際予備審査(または調査)機関に提出されたフレキシブルディスクによる配列表  
☐ 出願後に提出した書面による配列表が出願時における国際出願の開示の範囲を超える事項を含まない旨の陳述書の提出があった  
☐ 書面による配列表に記載した配列とフレキシブルディスクによる配列表に記録した配列が同一である旨の陳述書の提出があった。

4. 補正により、下記の書類が削除された。

- ☐ 明細書 第 \_\_\_\_\_ ページ  
☐ 請求の範囲 第 \_\_\_\_\_ 項  
☐ 図面 図面の第 \_\_\_\_\_ ページ/図

5. ☐ この国際予備審査報告は、補充欄に示したように、補正が出願時における開示の範囲を越えてされたものと認められるので、その補正がされなかったものとして作成した。(PCT規則70.2(c) この補正を含む差し替え用紙は上記1.における判断の際に考慮しなければならず、本報告に添付する。)

## V. 新規性、進歩性又は産業上の利用可能性についての法第12条(PCT35条(2))に定める見解、それを裏付ける文献及び説明

## 1. 見解

新規性 (N)	請求の範囲	1-12, 14, 15, 18-40	有
	請求の範囲	13, 16, 17	無
進歩性 (IS)	請求の範囲	1-12, 18-40	有
	請求の範囲	13-17	無
産業上の利用可能性 (IA)	請求の範囲	1-40	有
	請求の範囲		無

## 2. 文献及び説明 (PCT規則70.7)

## ・ 請求の範囲 13-17 について

文献1 : OHTANI, K., et al., Toxicon(1988), Vol. 26, No. 11, p. 1107-1111

文献2 : ABOUZIED, M. M., et al.  
Applied and Environmental Microbiology(1993), Vol. 59, p. 1264-1268

文献3 : CASALE W. L., et al. Journal of Agricultural and Food Chemistry  
(1988), Vol. 36, No. 3, p. 663-668

文献4 : NICOL, M. J., et al.  
Food & Agricultural Immunology(1993), Vol. 5, No. 4, p. 199-209

文献1、Fig.1には、T-2トキシンとプロテイン複合体の作製方法であって、T-2の4位はOAcであり、15位にはOAcが結合しており、T-2の3位の水酸基をアシルオキシに変換した化合物の3位にプロテインを結合させることが記載されている。また、第1109頁第28行-第1110頁第1行及び第1110頁第13-16行には、ハプテン-プロテイン複合体がハプテンに結合する抗体作製及びスクリーニングのために使用されることが示唆されている。

文献2、Fig.1には、DNIVにプロテインを結合させる方法であって、DNIVの4位はOAcであり、15位にはOAcが結合しており、DNIVの3位の水酸基をアシルオキシに変換した化合物にプロテインを結合させることが記載されている。また、MATERIALS AND METHODS中Immunizationの欄にはDNIV-プロテイン複合体を抗体作製に使用することが記載されている。

補充欄 (いずれかの欄の大きさが足りない場合に使用すること)

## 第 V 欄の続き

文献3には、DONに対するモノクローナル抗体の作製の際に、DONとBSA複合体がマウスに投与されハイブリドーマが得られることが記載されており、またキャリア蛋白とDONの複合体は3-O-hemisuccinyl-DON (3-HS-DON) と蛋白質とを結合させることにより作製することが記載されている。

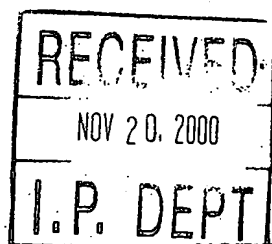
文献4には、DON-プロテイン複合体を作製する際に、3-HG-DONとプロテインとを結合させることが記載されている。また、作製された複合体は、DONに対するモノクローナル抗体作製の際にマウスに投与されハイブリドーマを得ることが記載されている。

文献3, 4には、DONの3位にキャリア蛋白を結合させた複合体をモノクローナル抗体作製に使用することが記載されており、請求の範囲13, 16及び17に記載された発明は、新規性を有さない。

文献1, 2には、文献1, 2において作製された複合体を使用したモノクローナル抗体産生ハイブリドーマの作製についての記載は存在しないが、周知の抗体作製技術を利用してモノクローナル抗体を産生するハイブリドーマを作製することは当該技術分野の専門家にとっては自明のものである。

・請求の範囲1-12, 18-40について

請求の範囲1, 3, 5に記載されたモノクローナル抗体またはその抗体断片、及び前記モノクローナル抗体またはその抗体断片を使用する免疫測定に関する構成は、国際調査報告に表示した文献のいずれにも記載も示唆もされていない。



## PCT COOPERATION TREATY

WPBJD

PCT

From the INTERNATIONAL BUREAU

To:

IWAHASHI, Kazuyuki  
Kyowa Hakko Kogyo Co., Ltd.  
Intellectual Property Dept.  
6-1, Ohtemachi 1-chome  
Chiyoda-ku  
Tokyo 100-8185  
JAPON

NOTIFICATION CONCERNING  
SUBMISSION OR TRANSMITTAL  
OF PRIORITY DOCUMENT

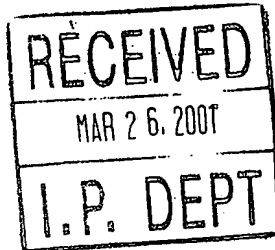
(PCT Administrative Instructions, Section 411)

Date of mailing (day/month/year) 08 November 2000 (08.11.00)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 1230	
International application No. PCT/JP00/06100	International filing date (day/month/year) 07 September 2000 (07.09.00)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 07 September 1999 (07.09.99)
Applicant KYOWA MEDEX CO., LTD. et al	

- The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
- An asterisk(\*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed to Rule 17.1(c)** which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed to Rule 17.1(c)** which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
07 Sept 1999 (07.09.99)	11/253443	JP	27 Octo 2000 (27.10.00)
29 Octo 1999 (29.10.99)	11/310185	JP	27 Octo 2000 (27.10.00)

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. (41-22) 740.14.35</p>	<p>Authorized officer</p> <p>S. Mandallaz</p> <p>Telephone No. (41-22) 338.83.38</p>
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## PATENT COOPERATION TREATY

PCT/JP00/06100  
WO 01/18196WPCJD  
PLPJD

PCT

From the INTERNATIONAL BUREAU

To:

IWAHASHI, Kazuyuki  
Kyowa Hakko Kogyo Co., Ltd.  
Intellectual Property Dept.  
6-1, Ohtemachi 1-chome  
Chiyoda-ku  
Tokyo 100-8185  
JAPONNOTICE INFORMING THE APPLICANT OF THE  
COMMUNICATION OF THE INTERNATIONAL  
APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence) PCLD

Date of mailing (day/month/year) 15 March 2001 (15.03.01)		IMPORTANT NOTICE	
Applicant's or agent's file reference 1230			
International application No. PCT/JP00/06100	International filing date (day/month/year) 07 September 2000 (07.09.00)	Priority date (day/month/year) 07 September 1999 (07.09.99)	
Applicant KYOWA MEDEX CO., LTD. et al			

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:  
AU, KR, US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:  
AE, AG, AL, AM, AP, AT, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EA, EE, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OA, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU,  
The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).
3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 15 March 2001 (15.03.01) under No. WO 01/18196

**REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)**

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

**REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))**

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer J. Zahra
Facsimile No. (41-22) 740.14.35	Telephone No. (41-22) 338.83.38



## PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU,

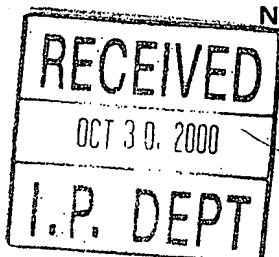
To:

IWAHASHI, Kazuyuki  
Kyowa Hakko Kogyo Co., Ltd.  
Intellectual Property Dept.  
6-1, Ohtemachi 1-chome  
Chiyoda-ku  
Tokyo 100-8185  
JAPON

NOTIFICATION OF RECEIPT OF  
RECORD COPY

(PCT Rule 24.2(a))

WPAJD



Date of mailing (day/month/year) 28 September 2000 (28.09.00)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 1230	International application No. PCT/JP00/06100

The applicant is hereby notified that the International Bureau has received the record copy of the international application as detailed below.

Name(s) of the applicant(s) and State(s) for which they are applicants:

KYOWA MEDEX CO., LTD. (for all designated States except US)  
KOHNO, Hiroaki et al (for US)

International filing date : 07 September 2000 (07.09.00)  
Priority date(s) claimed : 07 September 1999 (07.09.99)  
29 October 1999 (29.10.99)

Date of receipt of the record copy  
by the International Bureau : 22 September 2000 (22.09.00)

List of designated Offices :

AP : GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW  
EA : AM, AZ, BY, KG, KZ, MD, RU, TJ, TM  
EP : AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE  
OA : BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG  
National : AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE,  
ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,  
MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ,  
VN, YU, ZA, ZW

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer:

Masashi HONDA

Telephone No. (41-22) 338.83.38

## Continuation of Form PCT/IB/301

## NOTIFICATION OF RECEIPT OF RECORD COPY

Date of mailing (day/month/year) 28 September 2000 (28.09.00)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 1230	International application No. PCT/JP00/06100

**ATTENTION**

The applicant should carefully check the data appearing in this Notification. In case of any discrepancy between these data and the indications in the international application, the applicant should immediately inform the International Bureau.

In addition, the applicant's attention is drawn to the information contained in the Annex, relating to:

- ☒ time limits for entry into the national phase
- ☒ confirmation of precautionary designations
- ☒ requirements regarding priority documents

A copy of this Notification is being sent to the receiving Office and to the International Searching Authority.

## 国際調査報告

(法8条、法施行規則第40、41条)  
〔PCT18条、PCT規則43、44〕

出願人又は代理人 の書類記号 1230	今後の手続きについては、国際調査報告の送付通知様式(PCT/ISA/220)及び下記5を参照すること。	
国際出願番号 PCT/JPO0/06100	国際出願日 (日.月.年) 07.09.00	優先日 (日.月.年) 07.09.99
出願人(氏名又は名称) 協和メデックス株式会社		

国際調査機関が作成したこの国際調査報告を法施行規則第41条(PCT18条)の規定に従い出願人に送付する。  
この写しは国際事務局にも送付される。

この国際調査報告は、全部で 3 ページである。

☐ この調査報告に引用された先行技術文献の写しも添付されている。

## 1. 国際調査報告の基礎

a. 言語は、下記に示す場合を除くほか、この国際出願がされたものに基づき国際調査を行った。

☐ この国際調査機関に提出された国際出願の翻訳文に基づき国際調査を行った。

b. この国際出願は、ヌクレオチド又はアミノ酸配列を含んでおり、次の配列表に基づき国際調査を行った。

☐ この国際出願に含まれる書面による配列表

☐ この国際出願と共に提出されたフレキシブルディスクによる配列表

☐ 出願後に、この国際調査機関に提出された書面による配列表

☐ 出願後に、この国際調査機関に提出されたフレキシブルディスクによる配列表

☐ 出願後に提出した書面による配列表が出願時における国際出願の開示の範囲を超える事項を含まない旨の陳述書の提出があった。

☐ 書面による配列表に記載した配列とフレキシブルディスクによる配列表に記録した配列が同一である旨の陳述書の提出があった。

2. ☐ 請求の範囲の一部の調査ができない(第I欄参照)。

3. ☐ 発明の単一性が欠如している(第II欄参照)。

4. 発明の名称は ☒ 出願人が提出したものを承認する。

☐ 次に示すように国際調査機関が作成した。

5. 要約は ☒ 出願人が提出したものを承認する。

☐ 第III欄に示されているように、法施行規則第47条(PCT規則38.2(b))の規定により国際調査機関が作成した。出願人は、この国際調査報告の発送の日から1カ月以内にこの国際調査機関に意見を提出することができる。

6. 要約書とともに公表される図は、

第 \_\_\_\_\_ 図とする。 ☐ 出願人が示したとおりである。

☒ なし

☐ 出願人は図を示さなかった。

☐ 本図は発明の特徴を一層よく表している。